

direct customers, Parke-Davis ships orders via common carriers to customers. Parke-Davis' terms of sale provide that the prescription drugs are shipped "FOB point of origin." Therefore, title to the products passes to the customers at Parke Davis' warehouses.

7. Pfizer's sales of prescription drugs pursuant to the Federal Supply Schedule are not conducted pursuant to the standard published terms of sale described in Exhibit A. Rather, the title to products sold pursuant to the Federal Supply Schedule passes to Pfizer's customer upon delivery to the customer.

8. On August 4, 2000, Pfizer received the letter dated August 2, 2000 from Kevin W. Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit B.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT
THE FOREGOING IS TRUE AND CORRECT.

DATED: August 9, 2000

/s/
Thomas M. McPhillips

[Exhibit A]



U.S. Pharmaceuticals

**Wholesaler
Price List****General Offices:**

PFIZER U.S. PHARMACEUTICALS
235 East 42nd Street, New York, New York 10017
(212) 573-2323

DISTRIBUTION CENTERS:

1855 N. Shelby Oaks Drive, Memphis, Tennessee 38134
100 Jefferson Road, Parsippany, New Jersey 07054
16700 Red Hill Avenue, Irvine, California 92714
Toll-Free Order Number (800) 533-4535

Effective
January 11, 2000

A-078



U.S. Pharmaceuticals

GENERAL INFORMATION: ORDERS AND CORRESPONDENCE

All orders, and any correspondence pertaining thereto, are to be sent to:

Pfizer Inc.
Memphis Logistics Center
1855 N. Shelly Oaks Drive
Memphis, TN 38134
Attn: Pharmaceuticals Customer Service
(1-800-533-4535)

All orders, whether based upon submitted quotations or not, are subject to acceptance and credit approval by the company. We reserve the right to restrict order quantities.

PRICES

All prices are submitted without offer.

TERMS OF SALE

2% 30 days D.O.I. (date of invoice) net 45 days.
Electronically — 2% 35 days D.O.I. (date of invoice) net 50 days.

MINIMUM ORDER/ORDER FREQUENCY

All orders totaling less than \$500.00 net will be subject to a \$5.00 service charge. Under both terms, payment must be in the bank on the discount date. Accounts are limited to two orders per week. Orders in excess of the maximum will be subject to a \$5.00 service charge.

SHIPPING AND ROUTING

On orders where we pay transportation charges, we reserve the privilege of shipping via carrier of our own choice. Where special handling or routing is requested, the difference in transportation charges will be charged to the customer.

DELIVERY

All deliveries shall be made F.O.B. point of shipment. Title to the goods sold shall pass upon delivery of the goods to the carrier.

DAMAGE OR DELAY IN TRANSIT

If merchandise arrives in broken or damaged condition, insist upon the carrier's agent noting the damage or breakage on the delivery receipt. The transportation company acts as the agent of the purchaser, and we are not responsible for loss of, damage to, or delay respecting the goods after delivery to the carrier. We shall be pleased to assist, when requested, in formulating claims against the carrier, but we cannot assume the responsibility of collecting them.

RETURN GOODS POLICY

Products may be returned on the following basis:

I. Returnable Items: The following products are returnable by customers without prior approval:

- Outdated and discontinued merchandise, in the original container and bearing the original label.
- Product damaged in transit, subject to the above paragraph.
- Material shipped in error by Pfizer.

Notes: no credit will be issued for merchandise returned more than 12 months beyond expiration.

II. Non-Returnable Items: Product other than that listed above is defined as not returnable. This includes, but is not limited to:

- In-date product.
- Packages with label removed.
- Repackaged product.
- Product that has been in a fire, clearance, bankruptcy, or similar sale.
- Product sold on a "non-returnable" basis.
- Products retained more than twelve months beyond the expiration date noted on the package. (Product may be returned for destruction, but no credit will be issued.)
- Merchandise purchased or otherwise obtained in violation of any Federal, State, or local law or regulation.
- Merchandise destroyed or damaged from insurable causes such as fire, water, tornado, etc., and merchandise that has otherwise deteriorated due to conditions occurring after shipment and beyond the control of the manufacturer, such as improper storage, heat, cold, smoke, etc.

Notes: The Company's determination as to the salvage, credit or exchange value of merchandise returned shall be final. The

Company reserves the right to destroy returned merchandise without payment or liability.

III. Procedure for Returning Pfizer U.S. Pharmaceutical Group Products:

A. For all customers, returnable items may be returned without prior authorization by Company representative. Whenever you wish to return these items, pack the material in a container suitable for shipment, and include a packing list that identifies each item being returned, the name and address of your company, and Pfizer account number. All returns shall be made in compliance with all applicable Federal and State laws and regulations. Non-direct customers (i.e., those that purchase primarily through wholesalers), see note C1 and C2 for additional credit information.

The address for returns is:

Pfizer Inc.
Memphis Logistics Center
1855 N. Shelly Oaks Drive
Memphis, TN 38134
Attn: Return Goods

All products must be returned freight prepaid by the sender, using generally accepted shipment methods. Use a separate packing list for each carton to ensure acceptance and accurate credit. Upon receipt of the merchandise and verification of the contents and condition of the merchandise, a credit memorandum will be issued as appropriate. Credit will be issued at the lower of:

1. catalog or contract price in effect 12 months prior, or
2. the current replacement price, or
3. original purchase price.

Partial bottles may be returned, and credit will be issued in 25% increments to a maximum of 75% for any opened package.

B. Merchandise defined as Non-Returnable may be considered for exchange or credit (in full or partial) in the case of unusual circumstances. Prior approval is required by authorized Company personnel.

1. Customers with assigned Trade Development Managers should contact their Trade Development Manager.
2. All others should contact Customer Service at the address/phone number listed above.

C. Additional information for specific types of customers:

1. Hospitals, Clinics, Government facilities, and other contract-price entities: The Prescription Drug Marketing Act (PDMA) places specific restrictions on the return of pharmaceutical products from hospitals, healthcare entities and charitable institutions. The following applies to those returns in compliance with the PDMA guidelines. If products were purchased from a wholesaler under a prime vendor contract, you may request that we issue a credit invoice to you through a specific wholesaler. If you choose this option, you must supply the following information with your return: your customer number, your hospital DEA number and/or HIN number, your buying group association name, and the prime vendor wholesaler to receive credit. If products were purchased at contract prices direct from Pfizer, then applicable credit will be issued to your direct account number, or to your preferred wholesaler if you supply the information requested above.

2. Non-Direct Retail Accounts: Customarily, returned goods are channeled through the source of purchase. However, returnable merchandise may be returned direct to Pfizer, and appropriate credit will be issued through your preferred wholesaler. In order to receive credit when returning merchandise, a non-direct account must list the merchandise being returned on a sheet of paper that identifies the pharmacy name, address and the desired wholesaler, name and address through which a credit invoice should be issued. Should no wholesaler be identified, Pfizer reserves the right to issue no credit. Pfizer cannot be responsible for the application of the credit from the wholesaler to the specific non-direct account.



U.S. Pharmaceuticals

NATIONAL SALES DRUG CODE CODE	POTENCY	PKGS PER CASE	PKG SIZE	PRICE PER PKG
Antivert® (Metoclopramide HCl) Tablets B				
4864 0049-2100-66	12.5 mg	48	100's	\$33.03
4870 0049-2100-82	12.5 mg	24	1000's	\$13.35
4173 0049-2110-66	25 mg	48	100's	\$2.22
4880 0049-2110-82	25 mg	12	1000's	\$95.73
4871 0049-2140-66	50 mg	48	100's	\$6.24
Aricept® (Donepezil HCl) Tablets B				
7000 62856-245-30	5 mg	48	30's	104.29
7001 62856-246-30	10 mg	48	30's	104.29
Aricept® (Donepezil HCl) Tablets Unit-Dose B				
7002 62856-245-41	5 mg	12	(10x10)	347.62
7003 62856-246-41	10 mg	12	(10x10)	347.62
Atarax® (Hydroxyzine HCl) Tablets B				
4341 0049-5600-66	Tablets 10 mg	48	100's	\$2.44
4351 0049-5610-66	Tablets 25 mg	48	100's	\$6.91
4353 0049-5610-73	Tablets 25 mg	48	500's	\$66.86
3527 0049-5620-66	Tablets 50 mg	48	100's	\$3.76
4358 0049-5630-66	Tablets 100 mg	48	100's	\$15.20
Atarax® (Hydroxyzine HCl) Syrup B				
4361 0049-5650-93	Syrup 10 mg/5 mg	8	Pint	\$9.61
Cardura® (Doxazosin Mesylate) Tablets B				
0302 0049-2750-66	1 mg	48	100's	\$2.17
0303 0049-2760-66	2 mg	48	100's	\$2.17
0304 0049-2770-66	4 mg	48	100's	\$6.25
0305 0049-2780-66	8 mg	24	100's	\$0.57
Cardura® (Doxazosin Mesylate) Tablets Unit-Dose Pak B				
0312 0049-2750-41	1 mg	12	100's	\$4.62
0306 0049-2760-41	2 mg	12	100's	\$4.62
0308 0049-2770-41	4 mg	12	100's	\$6.83
0310 0049-2780-41	8 mg	12	100's	\$3.27
Cefobid® (Cefoperazone sodium) B				
0658 0049-1201-63	1 gm IM / IV Vial	10	10's	\$36.44
0661 0049-1211-63	1 gm IV PBUL	10	10's	Discontinued
0659 0049-1202-63	2 gm IM / IV Vial	10	10's	\$70.85
0662 0049-1212-63	2 gm IV PBUL	10	10's	\$65.82
0677 0049-1219-26	10 gm Pharmacy Bulk Package	100	1's	\$129.73
Diabinese® (Chlorpropamide) Tablets B				
1737 0069-3930-66	100 mg	48	100's	\$32.86
2594 0069-3940-66	250 mg	48	100's	\$6.45
2587 0069-3940-71	250 mg	24	250's	\$66.37
2589 0069-3940-82	250 mg	12	1000's	\$66.23
Diffucan® (Fluconazole) Oral B				
1210 0049-3410-30	50 mg Tablets	48	30's	\$14.07
1201 0049-3420-30	100 mg Tablets	48	30's	\$19.25
1204 0049-3430-30	200 mg Tablets	48	30's	\$29.31
Diffucan® (Fluconazole) Parenteral B				
1206 0049-3371-26	200 mg / 100 mL Saline PBULs	4	6's	\$42.68
1212 0049-3435-26	200 mg / 100 mL Saline Bags	4	6's	\$42.68
1213 0049-3437-26	200 mg / 100 mL Dextrose Bags	4	6's	\$42.68
1207 0049-3372-26	400 mg / 200 mL Saline PBULs	4	6's	\$19.23
1214 0049-3436-26	400 mg / 200 mL Saline Bags	4	6's	\$19.23
1215 0049-3438-26	400 mg / 200 mL Dextrose Bags	4	6's	\$19.23
Diffucan® (Fluconazole) Oral Unit-Dose Pak B				
1202 0049-3420-41	100 mg UD Tablets	12	100's	\$67.50
1205 0049-3430-41	200 mg UD Tablets	12	100's	\$77.74
Diffucan® (Fluconazole) Oral Suspension B				
1222 0049-3440-19	10 mg/mL OS	24	2oz	\$4.43
1223 0049-3450-19	40 mg/mL OS	24	2oz	\$8.76
Diffucan® (Fluconazole) 150 mg Tablet B				
1235 0049-3500-79	150 mg Tablets	24	(1X12)	\$14.13
Feldene® (Piroxicam) Capsules B				
1280 0069-3220-66	10 mg	48	100's	\$39.27
1282 0069-3230-66	20 mg	48	100's	\$26.34
1294 0069-3230-73	20 mg	12	500's	\$166.75
Geocillin® (Carbenicillin indanyl sodium) equiv. to 382 mg carbenicillin B				
3654 0049-1430-66	Tablets	48	100's	\$66.90
Glucotrol® (Glipizide) Tablets B				
1742 0049-4110-66	5 mg	48	100's	\$2.84
1748 0049-4110-73	5 mg	24	500's	\$56.02
1744 0049-4120-66	10 mg	48	100's	\$6.30
1750 0049-4120-73	10 mg	24	500's	\$26.38
Glucotrol® (Glipizide) Tablets Unit-Dose Pak B				
1747 0049-4110-41	5 mg	24	100's	\$4.46
1749 0049-4120-41	10 mg	24	100's	\$3.32

† Pfizer is acting as agent for Eisai Inc. with respect to the sale of Aricept.® Aricept is a registered trademark of Eisai Co., Ltd.
 D Indicates discontinued.
 ✓ Products not taking a price increase.

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U.S. Pharmaceuticals

NATIONAL SALES CODE	DRUG CODE	POTENCY	PAGE PER CASE	PRICE PER CASE
Glucotrol® XL (Glipizide) Extended Release Tablets B				
7220	0049-1520-30	2.5 mg	48	30's \$8.52
7200	0049-1550-66	5 mg	48	100's 28.41
7201	0049-1550-73	5 mg	24	500's 142.11
7204	0049-1560-86	10 mg	48	100's 58.23
7205	0049-1560-73	10 mg	24	500's 281.12
Inject® Penicillin G (Penicillin G benzathine) Aqueous Suspension B				
✓ 1643	0049-0210-35	1.2 ML Units / 2mL	10	10's 47.80
Milapress® (Prazosin HCl) Capsules B				
4444	0069-4310-71	1 mg	24	250's 95.94
D 4450	0069-4310-62	1 mg	12	1000's Deleted
4445	0069-4370-71	2 mg	24	250's 133.58
4445	0069-4380-71	5 mg	12	250's 227.86
Minizide® 1 (1 mg Prazosin and 0.5 mg Polythiazide) Capsules B				
2396	0069-4300-66		48	100's 56.96
Minizide® 2 (2 mg Prazosin and 0.5 mg Polythiazide) Capsules B				
2397	0069-4320-66		48	100's 71.73
Minizide® 5 (5 mg Prazosin and 0.5 mg Polythiazide) Capsules B				
2398	0069-4360-66		24	100's 108.78
Nervase® (Thiothixene) Capsules B				
6501	0049-5710-66	1 mg	96	100's 35.22
6511	0049-5720-66	2 mg	96	100's 47.49
6521	0049-5730-66	5 mg	96	100's 74.27
6531	0049-5740-66	10 mg	96	100's 102.38
7486	0049-5770-66	20 mg	48	100's 143.85
Nervase® (Thiothixene HCl) Concentrate B				
D 5112	0049-5750-47	5 mg/mL	24	4 oz Deleted
Norvasc® (Amlodipine besylate) Tablets B				
5819	0069-1520-66	2.5 mg	24	90's 98.29
5820	0069-1530-66	5 mg	48	90's 98.29
5809	0069-1530-72	5 mg	48	300's 321.09
✓ 5821	0069-1540-66	10 mg	48	90's 156.56
Norvasc® (Amlodipine besylate) Tablets Unit-Dose Pack B				
5812	0069-1530-41	5 mg	24	100's 109.22
✓ 5813	0069-1540-41	10 mg	24	100's 173.96

D Indicates discontinued.
✓ Products not taking a price increase.

NATIONAL SALES CODE	DRUG CODE	POTENCY	PAGE PER CASE	PRICE PER CASE
Pfizerpen® (Penicillin G potassium) for Injection Buffered B				
✓ 7488	0049-0530-28	20 ML Units / Vial	25	1's \$8.07
✓ 1635	0049-0520-83	5 ML Units / Vial	10	10's 27.55
Procardia® (Nifedipine) Capsules B				
1473	0069-2800-66	10 mg	48	100's 56.13
1478	0069-2800-72	10 mg	24	300's 165.03
1478	0069-2510-66	20 mg	48	100's 101.00
Procardia XL® (Nifedipine) Extended Release Tablets B				
1487	0069-2850-66	30 mg	48	100's 114.12
1505	0069-2850-72	30 mg	48	300's 335.53
1517	0069-2850-94	30 mg	4	5000's 5,582.13
1488	0069-2860-66	60 mg	48	100's 197.48
1506	0069-2860-72	60 mg	24	300's 580.60
1518	0069-2860-94	60 mg	2	5000's 9,676.48
1502	0069-2670-66	90 mg	48	100's 227.86
Procardia XL® (Nifedipine) Extended Release Tablets Unit-Dose Pack B				
1492	0069-2850-41	30 mg	24	100's 127.15
1493	0069-2860-41	60 mg	24	100's 220.05
1514	0069-2670-41	90 mg	12	100's 253.82
Renese® (Polythiazide) Tablets B				
9259	0069-3750-66	1 mg	48	100's 38.21
9258	0069-3760-66	2 mg	48	100's 50.00
9270	0069-3770-66	4 mg	48	100's 83.58
Sinequan® (Doxepin HCl) Capsules B				
4238	0049-5340-66	10 mg	48	100's 31.37
5508	0049-5350-66	25 mg	96	100's 40.47
D 7685	0049-5350-94	25 mg	1	5000's Deleted
7378	0049-5380-66	50 mg	48	100's 56.96
7686	0049-5390-94	50 mg	1	5000's 2,435.90
8021	0049-5390-66	75 mg	48	100's 94.48
9598	0049-5390-66	100 mg	48	100's 103.01
2604	0049-5370-50	150 mg	48	50's 85.52
Sinequan® (Doxepin HCl) Oral Concentrate B				
7607	0049-5100-47	10 mg/mL	24	120 mL 23.58
Tee® (Troleandomycin) Capsules B				
7647	0049-1590-66	250 mg	48	100's 99.65
Terra-Cort® (Doxycycline HCl and hydrocortisone acetate) Ophthalmic Suspension B				
D 5581	0049-0670-46	5 mL	30	1's Deleted

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U.S. Pharmaceuticals

NATIONAL SALES DRUG CODE CODE	POTENCY	PKGS PER CASE	PKG SIZE	PRICE PER PKG
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Tetracycline (Oxytetracycline HCl) Capsules \mathcal{B}				
D 0235 0069-0730-06	250 mg	48	100's	Deletad

Tetracycline (Oxytetracycline) Intramuscular Solution \mathcal{B}				
8885 0049-0750-77	50 mg/10 mL Vial	20	5's	\$38.91

Tetracycline Ophthalmic Ointment with Polymyxin B Sulfate (Oxytetracycline HCl with polymyxin B sulfate) \mathcal{B}				
2527 0049-0801-08	1/8 oz.	144	1's	7.83

Trovan[®] (Trovanoxacin mesylate) Tablets \mathcal{B}				
6212 0049-3780-30	100 mg	48	30's	146.56
6213 0049-3780-30	200 mg	48	30's	177.41

Trovan[®] (Trovanoxacin mesylate) Tablets Unit-Dose Box \mathcal{B}				
6214 0049-3780-43	100 mg	24	40's	195.40
6215 0049-3780-43	200 mg	24	40's	236.54

Trovan[®] (Axitroloxacin mesylate injection) IV Vials \mathcal{B}				
6203 0049-3890-28	200 mg	24	1's	30.34
6204 0049-3900-28	300 mg	24	1's	45.77

Unasyn[®] (Ampicillin sodium / sulbactam sodium) \mathcal{B}				
1647 0049-0013-83	1.5 g IM / IV Vial	10	10's	61.22
1648 0049-0022-83	1.5 g IV PBV	6	10's	70.96
1651 0049-0031-83	1.5 g ADD-Vantage [®] Vials	24	10's	64.96
0181 0049-0014-83	3 g IM / IV Vial	10	10's	116.56
1649 0049-0023-83	3 g IV PBV	6	10's	125.86
1655 0049-0032-83	3 g ADD-Vantage [®] Vials	24	10's	119.29
1657 0049-0024-28	15 gm Pharmacy Bulk Pkg.	25	1	57.79

Urobic[®] 250 (250 mg Oxytetracycline HCl, 250 mg sulfamethizole, and 50 mg phenazopyridine HCl) \mathcal{B}				
9545 0049-0820-50	Capsules	24	50's	69.46

Viagra[®] (Sildenafil citrate) Tablets \mathcal{B}				
4000 0069-4200-30	25 mg	24	30's	216.51
4001 0069-4210-30	50 mg	48	30's	216.51
4005 0069-4210-66	50 mg	48	100's	721.70
4002 0069-4220-30	100 mg	48	30's	216.51
4006 0069-4220-66	100 mg	48	100's	721.70

Vibramycin[®] Calcium (Doxycycline calcium oral suspension) Syrup \mathcal{B}				
6188 0069-0871-93	50 mg / 5 mL	6	1 Pint	151.45

NATIONAL SALES DRUG CODE CODE	POTENCY	PKGS PER CASE	PKG SIZE	PRICE PER PKG
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Vibramycin[®] Hyclate (Doxycycline hyclate) Capsules \mathcal{B}				
6278 0069-0940-50	50 mg	96	50's	\$91.05
6279 0069-0950-50	100 mg	48	50's	163.67
D 0286 0069-0950-75	100 mg	12	500's	Deletad

Vibramycin[®] Monohydrate (Doxycycline monohydrate) for Oral Suspension \mathcal{B}				
* 6277 0069-0870-85	25 mg / 5 mL	48	2 oz.	9.98

Vibra-Tab[®] (Doxycycline hyclate) \mathcal{B}				
6081 0069-0980-50	100 mg	48	50's	163.67

Vistaril[®] (Hydroxyzine pamoate) Capsules \mathcal{B}				
4373 0069-5410-66	25 mg	48	100's	76.91
4375 0069-5420-66	50 mg	48	100's	93.78
4377 0069-5430-66	100 mg	48	100's	115.20

Vistaril[®] (Hydroxyzine HCl) Intramuscular Solution \mathcal{B}				
6248 0049-5460-74	50 mg / mL 10 mL Vial	100	1's	15.45

Vistaril[®] (Hydroxyzine pamoate) Oral Suspension \mathcal{B}				
4367 0069-5440-83	25 mg / 5 mL	6	1 Pint	117.25
2418 0069-5440-87	25 mg / 5 mL	12	4's	117.35

Zithromax[®] (Azithromycin) Tablets \mathcal{B}				
6428 0069-3080-30	250 mg	24	30's	162.13
6440 0069-3080-30	600 mg	24	30's	389.06

Zithromax[®] (Azithromycin) Tablets Z-PAK[®] \mathcal{B}				
6438 0069-3080-75	250 mg	12	(3x4)	97.30

Zithromax[®] (Azithromycin) Tablets Unit-Dose Pak \mathcal{B}				
6421 0069-3080-88	250 mg	12	50's	270.23

Zithromax[®] (Azithromycin) 1 gm Single Dose Pak \mathcal{B}				
6427 0069-3051-75	1 gm	12	3	50.35
6413 0069-3051-07	1 gm	12	10	167.84

Zithromax[®] (Azithromycin for oral suspension) \mathcal{B}				
6415 0069-3110-19	300 mg (100 mg / 5 mL)	24	1	22.86
6416 0069-3120-19	600 mg (200 mg / 5 mL)	24	1	22.86
6417 0069-3130-19	900 mg (200 mg / 5 mL)	24	1	22.86
6424 0069-3140-19	1200 mg (200 mg / 5 mL)	24	1	22.86

Zithromax[®] LV (Azithromycin for injection) \mathcal{B}				
6445 0069-3150-83	500 mg Vial	10	10	195.55

D Indicates discontinued.
✓ Products not taking a price increase.

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U.S. Pharmaceuticals

NATIONAL SALES CODE	DRUG CODE	POTENCY	PBS PER CASE	PKG SIZE	PRICE PER PKG
Zoloft® (Sertraline HCl) Tablets 33					
3641	0049-4900-50	25 mg	48	50's	\$90.71
3600	0049-4900-66	50 mg	48	100's	187.34
3618	0049-4900-73	50 mg	24	500's	936.62
3628	0049-4900-94	50 mg	1	5000's	9,366.40
3602	0049-4910-66	100 mg	48	100's	192.76
3619	0049-4910-73	100 mg	24	500's	963.76
3627	0049-4910-94	100 mg	1	5000's	9,637.56

NATIONAL SALES CODE	DRUG CODE	POTENCY	PBS PER CASE	PKG SIZE	PRICE PER PKG
Zoloft® (Sertraline HCl) Tablets Unit-Dose Pak 33					
3601	0049-4900-41	50 mg	12	100's	\$187.34
3603	0049-4910-41	100 mg	12	100's	192.76
Zyrtec® (Cetirizine HCl) Syrup 33					
5715	0069-5530-47	(1 mg / 1 mL)	24	120mL	22.42
5716	0069-5530-53	(1 mg / 1 mL)	6	Flex	89.65
Zyrtec® (Cetirizine HCl) Tablets 33					
5700	0069-5500-86	5 mg	48	100's	153.41
5701	0069-5510-86	10 mg	48	100's	153.41

D Indicates discontinued.

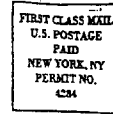
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**Pfizer Pharmaceuticals Product
Liability Protection Policy**

In the event of a claim or lawsuit arising out of the dispensing of a Pfizer Pharmaceuticals product, it is Pfizer's policy to defend and hold harmless the pharmacist or the pharmacist's employer if the following conditions are met:

- if a prescription product, the prescription was properly filled by the pharmacist;
- the product was not improperly stored or packaged;
- there is no evidence of negligence or any improper or illegal act by the pharmacist or employer;
- the pharmacist has not made express warranties nor provided information inconsistent with the approved product labeling;
- the pharmacist and the pharmacist's employer, if any, provide Pfizer with prompt notice of the claim or lawsuit and fully cooperates with Pfizer in the defense of the claim or lawsuit.

Pfizer
235 East 42nd Street
New York, NY 10017



U.S. Pharmaceuticals

Important Price Information

A-085

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA

Plaintiff,

v.

Civil Action No. _____

KEVIN CONCANNON, in his official capacity
as Commissioner of the Department of Human
Services for the State of Maine

ANDREW KETTERER, in his official capacity
as Attorney General for the State of Maine

Defendants.

DECLARATION OF JUDITH L. TEMPEL
IN SUPPORT OF PLAINTIFF'S MOTION
FOR PRELIMINARY INJUNCTION

1. My name is Judith L. Tempel. From May 1, 2000 to present, I have served as the Manager of Distribution Operations of Eli Lilly and Company ("Lilly").

2. Lilly is a corporation organized and existing under the laws of Indiana that maintains its principal place of business in Indianapolis, Indiana.

3. I have been an employee with Lilly for nine (9) years serving in various roles prior to my current position. I received my Masters in Civil Engineering from Purdue University in Indiana in 1990.

4. I am filing this Declaration in support of Plaintiffs Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for

Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

5. I am knowledgeable about Lilly's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Lilly's sales of prescription drugs in Maine.

6. All sales of Lilly's prescription drugs by Lilly occur outside Maine through direct, arms-length, transactions with authorized, independent wholesalers or distributors. Orders for all Lilly products from authorized wholesalers for distribution in the United States are filled for distribution from the Lilly warehouses located in Connecticut, Indiana and California. In accordance with the terms of Lilly's standard agreement with wholesalers ("Agreement"), the warehouse delivers the prescription drugs to the wholesalers or distributors on the loading dock of Lilly's warehouse. As is stated in the Agreement, title to the prescription drugs passes to the wholesaler or distributor upon delivery to the wholesaler or distributor at the Lilly warehouse. Wholesalers make payments for the prescriptions drugs purchased pursuant to the Agreement by electronic transfer to Lilly through Mellon Bank in Pittsburgh, Pennsylvania. Wholesalers and distributors sell the prescription drugs to their customers who are located throughout the country, including customers in the state of Maine, in separate, independent transactions. The wholesalers and distributors do not act on behalf of Lilly in the resale of the prescription drugs. From time to time, at the request of the wholesaler or distributor (or in the case of Lilly's growth hormone product, Humatrope®, the relevant health care facility or treating physician's office), Lilly may ship product directly to a particular end customer of a wholesaler or distributor, but the terms of the sale are governed by the same Agreement provisions, and the wholesaler or distributor are responsible for payment. Lilly's policy of selling its products in this manner has been in place for at least three (3) years.

7. On or about August 4, 2000, Lilly received the letter dated August 2, 2000 from Kevin W, Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit A.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT
THE FOREGOING IS TRUE AND CORRECT.

DATED: August 9, 2000

/s/

Judith L. Tempel
Manager of Distribution Operations
Eli Lilly and Company

[Exhibit A]

Angus S. King, Jr.
Governor

Kevin W. Concannon
Commissioner

State Of Maine
DEPARTMENT OF HUMAN SERVICES
Augusta, Maine 04333

August 2, 2000

RICHARD L. BROWN, MC255
ELI LILLY AND COMPANY
LILLY CORPORATE CENTER

INDIANAPOLIS, IN 46285

Dear RICHARD L. BROWN, MC255,

I am writing to you on behalf of the State of Maine, Department of Human Services. I want to inform you about the new Maine Rx Program and invite you to participate in the rebate program for this initiative. I am enclosing a copy of the law, Public Law 1999, chapter 786, for your review.

The Governor and the Legislature passed this new law, during the past legislative session, which goes into effect on January 1, 2001. Under the Maine Rx program the State will serve as a pharmaceutical benefit manager (PBM) for the estimated 325,000 Maine residents who have no prescription drug benefit as part of a private or public health insurance program. Those residents would be eligible to receive a Maine Rx card.

The Maine Rx Program would provide your company's products to an ever growing population and a population that would exceed the current Medicaid population, which is currently 170,000 people. This means greater access to and utilization of your pharmaceuticals.

You will also find a rebate agreement enclosed. I am requesting you sign and return this agreement as soon as possible, but not later than November 1, 2000, so your company's products may be included in the Maine Rx Program for the January 1, 2001 start date. This law also addresses profiteering, unfair trade practices, and requires the Department impose prior authorization requirements in the Medicaid Program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers who do not enter into rebate agreements.

Also to be noted, the names of manufacturers and labelers who do not enter into rebate agreements pursuant to this law are public information. Your company has the opportunity to assist those Maine citizens with a real need for affordable prescription drugs. An added benefit to participating is your company gains nationwide recognition as a participant in the Maine Rx Program. This Program has received nationwide press attention and will continue to do so in the foreseeable future.

Thank you for your continued support of Maine Pharmacy Programs and for your concern for the prescription drug needs of all Maine citizens.

We look forward to working with you, and should you have any questions concerning this Program, feel free to call Jude Walsh, Director, Division of Quality Improvement at (207)287-1815 for our direct assistance.

Sincerely,

 /s/

Kevin W. Conannon, Commissioner

Enclosures: PL 786
Rebate Agreement

MAINE RX PROGRAM REBATE AGREEMENT

BETWEEN

THE COMMISSIONER OF THE DEPARTMENT OF
HUMAN SERVICES OF THE STATE OF MAINE

And

THE MANUFACTURER IDENTIFIED IN SECTION VIII

OF THIS AGREEMENT

(Hereinafter referred to as the “Manufacturer”)

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

- (a) “*AVERAGE WHOLESALE PRICE*” means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.
- (b) “*CALENDAR QUARTER*” means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 — March 31, 2001. Each successive three-month period shall be a Calendar Quarter.
- (c) “*COMMISSIONER*” means the Commissioner of the Department of Human Services.

- (d) “*DEPARTMENT*” means the Department of Human Services.
- (e) “*MANUFACTURER*” means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.
- (f) “*NATIONAL DRUG CODE (NDC)*” is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.
- (g) “*NET SALES*” means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.
- (h) “*PRESCRIPTION DRUG*” means (1) legend drugs, defined as drugs carrying the statement “Caution: Federal Law Prohibits Dispensing Without A Prescription” and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer’s labeler code segment of the National Drug Code (NDC).
- (i) “*QUALIFIED RESIDENT*” means a resident of the State who has obtained from the Department a Maine Rx enrollment card.
- (j) “*REBATE AMOUNT*” means the Medicaid Rebate amount.
- (k) “*REBATE PAYMENT*” means, with respect to the Manufacturer’s Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine

which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

- (1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.
 - (2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.
- (l) “UNIT” means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.
- (m) “UTILIZATION DATA” means the information regarding the total number of Units of each dosage form and strength of the Manufacturer’s Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.
- (n) “WHOLESALE PRICE (WP)” means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate

distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

- (o) "*WHOLESALE*" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

- (a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of

utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization. Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

- (b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.
- (c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.
- (d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The Manufacturer shall allow inspection of pertinent documents by the Department or any authorized

representative of the State of Maine, and shall furnish copies thereof, if requested.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

- (a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.
- (b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

- (a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.
- (b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense,

may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

- (c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.
- (d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.
- (e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

V. CONFIDENTIALITY PROVISIONS

- (a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices

charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.

- (b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Data, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.
- (c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

VI. TERMINATION

- (a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.
- (b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.
- (c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.
- (d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

- (e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

VII. GENERAL PROVISIONS

- (a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
 Director of Pharmacy Programs
 Bureau of Medical Services, 3rd Floor
 11 State House Station
 Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

- (b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.
- (c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, without any effect on any other provision.

- (d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.
- (e) The terms "Department: and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.
- (f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.
- (g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

VIII. MANUFACTURER'S ACCEPTANCE

I, _____ hereby agree to the terms
 (Name of Authorized Representative)
 of this Agreement for the following Manufacturer(s) and
 labeler(s):

_____ (Labeler Name)	_____ (Code)
_____ (Labeler Name)	_____ (Code)
_____ (Labeler Name)	_____ (Code)

(Labeler Name)

(Code)

(Signature)

(Title)

Date: _____

IX. COMMISSIONER'S CERTIFICATION

This is to certify that _____ is a
participant in the Maine Rx Program Rebate Program
effective _____.

Christine Zukas-Lessard

DATE: _____

Acting Director, Bureau of Medical Services
For the Commissioner

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS
OF AMERICA,

Plaintiff

v.

Civil Action No. ____

KEVIN CONCANNON, in his official
Capacity as Commissioner of the
Department of Human Services for
the State of Maine, and
ANDREW KETTERER, in his official
Capacity as Attorney General
for the State of Maine,

Defendants

AFFIDAVIT OF SCOTT HOWELL, M.D.
IN SUPPORT OF PLAINTIFFS
MOTION FOR A PRELIMINARY INJUNCTION

1. My name is Dr. Scott Howell. I am Vice President of National Accounts, Managed Care, SmithKline Beecham Corporation. An accurate copy of my resume is attached as Exhibit A to this Affidavit.

2. When prior authorization is required for a drug under a plan providing prescription drug coverage, a physician must obtain specific permission from the plan each time the physician wishes to prescribe the drug, or the pharmacist must obtain specific permission from the plan each time he or she is asked to fill a prescription for the drug. The purpose of requiring prior authorization is to limit the use of the drug.

3. Prior authorization is often employed by managed care organizations ("MCOs") to enforce a drug formulary and is

usually intended to limit the drugs to be prescribed by health care professionals. MCOs typically require health care professionals to obtain prior authorization from the MCO before prescribing a drug (1) to ensure proper use of prescription drugs with a high potential for inappropriate use, (2) to limit the use of prescription drugs with severe or life threatening side effects and/or drug interactions; and (3) to encourage the use of cost-effective medications without diminishing safety or efficacy.

4. Prior authorization is not supposed to be, and on information and belief has never been, utilized as a form of punishment and without considering safety, efficacy and the availability of other drugs. On information and belief, prior authorization has never been required for a drug under one prescription drug coverage, for the purpose of influencing the manufacturer's pricing behavior in another program. On information and belief; such a use of prior authorization—limiting access to the drug by patients who are covered by one program, in order to bring about lower prices for the drug to patients who are covered in another program—is unprecedented. This, however, in my opinion, is the obvious aim, and would be the inevitable effect, of the Maine Act challenged in this case.

5. Even when justified by the considerations described in paragraph 3, prior authorization does not come without a cost to the healthcare professional and the patient. Consequently, it is my opinion that application of the prior authorization process for the artificial punitive purpose contemplated by the Maine Act—unrelated to Medicaid patient care or even the administration of the Medicaid program—will impose significant and gratuitous burdens on Medicaid healthcare providers and patients, as a result of which those patients likely will not receive the safest and most efficacious drugs that they would otherwise receive. Unmoored from the considerations described in paragraph 3, it is my opinion that such prior authorization process will (1) lead to inappropriate

prescribing of medications for Medicaid patients, (2) needlessly burden doctors who treat Medicaid patients; and (3) cause unnecessary inconvenience for Medicaid patients.

6. In my opinion, prior authorization of drugs, without regard to safety or efficacy, will lead to drugs being prescribed that are less safe and efficacious. Healthcare professionals choose medicines for patients based on their understanding of their patients' needs and the efficacy and safety profile of the drugs. Prior authorization causes doctors to switch from first-choice drugs to potentially less safe and effective second-choice drugs. Even though healthcare professionals would not knowingly prescribe another drug that they expected to be ineffective or harmful to the patient, healthcare professionals would be forced to switch to drugs that have safety and efficacy profiles with which they are less familiar or may consider less desirable.

7. Suppose, for example, that, pursuant to the Maine Act, physicians in Maine were restricted from prescribing *Augmentin* for their Medicaid patients. *Augmentin*, a leading antibiotic used for ear infections in children, was recommended in national guidelines published by the CDC for such use. Less effective alternatives do exist, and if *Augmentin* were subject to prior authorization, then it is likely that Maine healthcare professionals would switch patients to these less effective drugs. They would do so believing in good faith that the patient will be cured. However, this will not be the case in some instances. Some patients will have resistant infections that withstood the less effective product; some will recover more slowly; and others will suffer complications needlessly.

8. An inappropriate implementation of prior authorization also needlessly burdens the healthcare professional. When physicians decide based upon their professional judgment that a drug, which is subject to prior authorization, is the best remedy for their patients, the physicians are required each time they choose to prescribe the drug to justify to the MCO

why that particular patient needs the drug and then to obtain the MCO's approval for that use. In this day of increasing burdens in healthcare, it is no small measure to unnecessarily add to the hassles of doctors. In fact, it harms them greatly and reduces time they can spend with their patients.

9. Such broad prior authorizations cause unnecessary hassles and anxiety for patients. In many instances, patients cannot immediately receive their prescriptions subject to this process. Patients many times are required to wait until the MCO approves it and must return to the pharmacy to retrieve the drugs if they are approved. Frequently, anxiety and confusion occurs with patients because they do not understand why the medicine their doctor chose for them has not been approved and requires a switch. This anxiety can be exacerbated in situations where the patient had used the drug previously. This, in turn, can lead to compliance problems for patients.

10. When prior authorizations are implemented properly, they can increase the clinical and cost-effectiveness of a drug formulary. When used wrongly, they cause harm to both patients and health professionals. Because of these sensitive factors, MCO's do not implement blanket prior authorizations without regard to safety, efficacy, and cost-effectiveness of the drugs. MCOs hire large pharmacy departments, convene formal committees with healthcare professionals, and seek outside expert advice to make such important decisions. The implementation of prior authorization under the Maine Act, by contrast, does not permit such a thoughtful process. Consequently, in my opinion, this will create a high likelihood that it will cause harm to patients and healthcare professionals.

11. Requiring prior authorization for SmithKline's drugs in the Medicaid program in Maine is likely to have an adverse effect on SmithKline's market share and sales beyond the Medicaid program. When physicians encounter an obstacle (such as prior authorization) to prescribing a drug under one

program or plan, the existence of that obstacle tends to discourage them from prescribing the drug even under programs or plans that do not impose such obstacles. Thus, for example, in our experience, the most restrictive formularies in an area become de facto formularies for the area generally. For that reason, the Maine Act would curtail access to SmithKline's drugs not only for Maine residents covered by the Medicaid program but for the general population of Maine covered by the Maine Rx Program, causing a correspondingly greater loss to SmithKline of market share and sales for the prior authorized drugs.

12. The foregoing is based on personal knowledge, other than that which is upon information and belief as described above.

I state under penalty of perjury that the foregoing is true and correct. Executed on August 9, 2000.

/s/
SCOTT HOWELL, M.D.

[Exhibit A]

HOWARD SCOTT HOWELL, MD, MBA

Home	861 Lesley Road Villanova, PA 19085 (610) 989-0949
Office	3FP0505, Three Franklin Plaza Philadelphia, PA 19101 (215) 751-7549
Personal	DOB: December 13, 1960 Married, one child
Education	
Undergraduate Education 1979-1983	The University of Notre Dame B.S. with high honors Pre-professional Studies
Medical Education 1983-1987	The Ohio State University M.D. magna cum laude
Internship and Residency 1987-1990	The Duke University Medical Center Internal Medicine
Graduate Education 1994-1996	The Fuqua School of Business Duke University M.B.A., Fuqua Scholar
Board Certification	Internal Medicine
Licensure	Ohio

Work History

1997-Present	SmithKline Beecham Pharmaceuticals Philadelphia, Pennsylvania Director/Vice President, Managed Care Division
1993-1997	The Ohio State University Medical Center Columbus, Ohio Medical Director of Ambulatory Care
1990-1993	Henderson County Internists Hendersonville, North Carolina Private Practice, General Internal Medicine

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH	*
AND MANUFACTURERS OF AMERICA	*
	*
Plaintiff,	*
v.	* Civil Action
	* No. _____
	*
KEVIN CONCANNON, in his official	*
capacity as Commissioner of the	*
Department of Human Services for the	*
State of Maine	*
	*
	*
ANDREW KETTERER, in his official	*
capacity as Attorney General for the	*
State of Maine	*
	*
Defendants.	*
	*
* * * * *	*

AFFIDAVIT OF DAVID MOULES
IN SUPPORT OF PLAINTIFF'S
MOTION FOR A PRELIMINARY INJUNCTION

1. My name is David Moules. I am Vice President and Director, National Accounts, Managed Care Division, SmithKline Beecham Pharmaceuticals ("SmithKline"). I have responsibility for SmithKline's national account customers in Health Maintenance Organization, Pharmacy Benefit Manager, Institutional (Hospital/GPO, Long Term Care), and Federal Accounts business segments. An accurate copy of my resume is attached as Exhibit A to this Affidavit.

2. SmithKline manufactures and markets pharmaceuticals, vaccines, over-the-counter medicines and health related consumer products. One of the world's leading healthcare companies, SmithKline employs 47,300 people worldwide with operations in 160 countries.

3. I am knowledgeable about SmithKline's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically the extent to which SmithKline sells its drugs in Maine.

4. Although drugs produced by SmithKline are sold in Maine, SmithKline itself does not sell any of its drugs in Maine. (SmithKline sells vaccines in Maine, but it is my understanding that these vaccines are not covered by the Maine statute at issue in this case. SmithKline also sells to federal facilities in Maine under the Federal Supply Schedule.) SmithKline sells its drugs to wholesalers/distributors, which are independent companies in which SmithKline has no ownership or other financial interest. None of these wholesalers/distributors is headquartered in Maine, and none of them maintains any warehouses in Maine to which SmithKline currently ships any of its drugs. SmithKline instead sells its drugs to these wholesalers/distributors in transactions in which the sale does not take place in Maine, but at locations outside of Maine where SmithKline delivers its drugs to common carriers that transport the drugs to the wholesalers'/distributors' Out of state warehouse.

5. Under the governing Wholesaler Distribution Agreement, an example of which is attached as Exhibit B to this affidavit, title passes from SmithKline to the wholesaler upon SmithKline's delivery of the drug to the common carrier at SmithKline's Tennessee distribution facility. In accordance with the terms of the Agreement, the warehouse then ships the order via common carrier (*i.e.*, Roadway Express, Federal Express, UPS) to the wholesaler or

distributor at a location outside the state of Maine. Although SmithKline will replace drugs lost or damaged during shipment, once the drug is delivered, the risk of loss passes to the wholesaler or distributor at its delivery site outside of Maine.

6. The SmithKline warehouse located in Knoxville, Tennessee fills electronic orders from wholesalers and distributors. SmithKline does not earmark its drugs for sale in particular states. To the contrary, under the terms of the Agreement, the wholesaler is free to sell drugs it has purchased from SmithKline to any customer (*e.g.*, a retail pharmacy) located anywhere in the country. Wholesalers and distributors sell the drugs to their customers who are located throughout the country, including customers in the state of Maine. The wholesaler/distributor does not act on behalf of SmithKline in the distribution chain.

7. I am also knowledgeable about the impact that prior authorization has on SmithKline's market share and sales. It is my opinion that the Maine Act threatens drug manufacturers with prior authorization in the Medicaid program if they decline to enter into rebate agreements with the state under Maine Act, precisely because the proponents of the statute understand that prior authorization severely and perhaps permanently damages a drug's market share and sales, and that, from a manufacturer's standpoint, avoiding prior authorization would therefore be a powerful incentive to enter into rebate agreements with the state.

8. The purpose of requiring prior authorization is to limit the use of the drug. When a drug is subject to prior authorization under a plan or program providing prescription drug coverage, each time a physician prescribes the drug for a patient, the physician is required to justify doing so to the administrator of the plan or program, and the prescription will not be covered under the plan or program without the administrator's approval. The circumstance under which

prior authorization is typically required are described in the Affidavit of Dr. Scott Howell.

9. As four examples demonstrate, requiring prior authorization with respect to a manufacturer's drug severely curtails patient access to the drug and sharply reduces the drug's market share and sales as the prior authorization shifts patients to competing drugs of other manufacturers that are not subject to prior authorization.

10. *Augmentin*. Augmentin is SmithKline's flagship antibiotic product, indicated for the treatment of infections caused by susceptible strains of bacteria in conditions such as lower respiratory tract infections, otitis media, sinusitis, skin and skin structure infections, and urinary tract infections. Patient access to Augmentin was sharply curtailed in the Las Vegas, NV market, and Augmentin sales in that market sharply dropped, when a prior authorization was put in place by the largest managed care organization in the metropolitan statistical area (over 100,000 lives). When the prior authorization was imposed in the first quarter of 1999, Augmentin had a 49% market share. Its market share two quarters after the PA was implemented was 18%. The prior authorization thus resulted in a 60.9% loss in market share.. Since implementation of the prior authorization, market share and sales have been significantly reduced and have not recovered. As a result of the prior authorization, SmithKline's cumulative loss in sales revenue at this health plan for the first full quarter in which the prior authorization was in effect was approximately \$272,000. See Exhibit C to this Affidavit.

11. *Paxil*. Paxil, another SmithKline product, is a selective serotonin reuptake inhibitor ("SSRI"), indicated for the treatment of depression, obsessive compulsive disorder, panic disorder, and social anxiety disorder. Patient access to Paxil was reduced, and Paxil market share and sales correspondingly fell, in numerous geographical areas when a prior authorization was imposed by a large national managed

care organization in the first quarter of 1997. When the prior authorization was imposed in the first quarter of 1997, Paxil had a 21% market share. Its market share two years later was 12%. The prior authorization thus resulted in a 41.8% loss of market share over the following eight quarters. As a result of PA, SmithKline's cumulative loss in sales revenue at this managed care organization over the eight quarters analyzed was approximately \$7 million. See Exhibit D. Only after this customer merged with another company and the prior authorization was removed in the third quarter of 1999 did sales in those geographical areas begin to recover.

12. *Relafen*. Relafen is SmithKline's nonsteroidal anti-inflammatory drug product ("NSAID") indicated for acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis. Patient access to Relafen was reduced, and Relafen's market share and sales correspondingly fell, in numerous geographies when a prior authorization was introduced by a large national managed care organization in the first quarter of 1998. When the prior authorization was imposed in the first quarter of 1998, Relafen had a 12.8% market share. Its market share two years later was 4.2%. The prior authorization resulted in a 67.2% loss of market share over the eight quarters after the time the prior authorization was implemented. Since implementation of the PA, sales and market share have been significantly reduced and have not recovered. As a result of the PA, SmithKline's cumulative loss in sales revenue at this managed care organization over the eight quarters analyzed was approximately \$2.9 million. See Exhibit E.

13. *Avandia*. Avandia is SmithKline's oral antidiabetic product indicated for glycemic control in patients with type 2 diabetes. Patient access to Avandia was reduced, and Avandia market share and sales correspondingly fell, when a prior authorization was implemented by a large managed care plan in March 2000. The prior authorization resulted in a

drop in market share of 46% just two months after the prior authorization was implemented. *See* Exhibit F.

14. It is SmithKline's experience that the injury caused by a prior authorization can linger even after the prior authorization is lifted. Market share, once lost, is difficult to recover and may never be recovered, as physicians and patients develop loyalty to competing drugs of other manufacturers not subject to the prior authorization while the prior authorization on the manufacturer's drug is in place. The result for the manufacturer whose drug is subject to the prior authorization may be a permanent loss of sales and market share and a permanent loss of good will.

I state under penalty of perjury that the foregoing is true and correct. Executed on August 9, 2000.

/s/
DAVID MOULES

[Exhibit A]

DAVID A. MOULES

PROFESSIONAL EXPERIENCE

SMITHKLINE BEECHAM

U.S. PHARMCEUTICALS – MANAGED CARE DIVISION:

April 1997 – Present

Vice President and Director, National Accounts

Member of the Managed Care Division leadership team with responsibility for the national account customers in the HMO, PBM, Institutional (Hospital/GPO, Long Term Care) and Federal Accounts business segments. Primary responsibilities include:

- Provide strategic direction for the “business segments” that are responsible for selling/servicing the National Account customers of SB Pharmaceuticals.
- Develop and implement strategies to achieve sales (gross and net) objectives.
- Oversee the development, implementation and execution of marketing/business plans for the National Account Business Segments.
- Collaborate with SB Pharmaceutical groups (Sales, Marketing, Contract Management, Medical Affairs, Legal, etc.) to ensure the development and delivery of contracts, programs, and services which meet customer needs and enhance customer relationships.
- Forecast, plan and develop business plan objectives and budgets.
- SB Pharmaceuticals “Senior Management” contact/liaison for National Account customers in the IMO, PBM, Institutional and Federal Accounts business segments.

- Recommend most appropriate organizational/operating policies and strategies to achieve desired results.
- Evaluate/approve contracting strategies designed to improve business segment sales and profitability results.
- Assist in the negotiation of key customer proposals and contract renewals.
- Facilitate the development of Managed Care National Accounts personnel by establishing and monitoring Major Business Objectives (MBO's) for each direct report (for performance and personal development).

SMITHKLINE BEECHAM

DIVERSIFIED PHARMACEUTICAL SERVICES: September 1994 – April 1997

Senior Vice President

Member of Diversified's Executive Management Team responsible for the strategic planning and overall management of existing and potential managed care (HMO) and non-managed care (e.g., employer, TPA, insurance, consumer) clients. Primary responsibilities included:

- Managing the sales process to meet new business and client retention objectives
- Implementing a sales organizational structure that allowed Diversified to meet business objectives
- Recruiting/training and managing a national sales organization
- Managing the financial aspects of the business to improve profitability

CIGNA HEAL THCARE: June 1987- September 1994

Sales Vice President: April 1992 - September 1994

Responsible for recruiting, training, and motivating a high performance sales force in order to achieve Division results in

revenue growth, profitability, membership growth, persistency and new firm growth. In addition, the position responsibilities included assisting in key sale opportunities; maintaining executive level contacts with customers and producers; developing and monitoring annual sales plans; analyzing competitive information and providing input on local market needs; executing the human resource management process; preparing budget and staffing plans; and, maintaining relationships with matrix partners.

Sales Director February 1991 - March 1992

In reporting to the Sales Vice President, I was responsible for the hiring, coaching, and training of sales representatives and other office staff. As a Sales Director in a District office, I had full responsibility for developing annual sales plans; overseeing the management of the book of business; executing the human resource management process; preparing and monitoring the budget and staffing plans; assisting in key sales situations; and, coordinating sales/service plans with matrix partners.

Group Marketing Executive: June 1987 - January 1991

Responsible for employee benefit sales and account management for medical, dental, disability and life insurance lines of business. In this role, I managed an existing book of business in excess of \$50 million in premium revenue; and was responsible for broadening the base of business through sales of both existing accounts as well as new firms. In addition, I was accountable for developing relationships for CIGNA within the employee benefits brokerage/consulting community.

SB
SmithKline Beecham
Pharmaceuticals

WHOLESALE DISTRIBUTION AGREEMENT

Agreement January 1, 1999, between SmithKline Beecham Pharmaceuticals, a division of SmithKline Beecham Corporation (SB), Philadelphia, Pennsylvania 19101, and

Company

including its branches referred to on the attached Exhibit A, with main offices located at

WHOLESALE.

Pursuant to this Agreement, SB appoints WHOLESALER as a distributor for its selected pharmaceutical products. The parties hereto, intending to be legally bound, hereby agree as follows:

I. OBLIGATIONS OF SB:

A. Shipment and Pricing to WHOLESALER

SB shall sell to WHOLESALER and shall ship selected products to the above address and to addresses specified in Exhibit A, attached hereto and incorporated by reference. SB shall charge WHOLESALER for SB products in accordance with the WHOLESALER prices and policies shown in the SB Wholesaler Price List plus all applicable Federal and State Taxes in effect on the date of SB's receipt of order.

B. Special Contract Pricing

SB shall adjust the Net Wholesale Purchase Prices for SB products sold and shipped from WHOLESALER'S inventory under contract sales for which SB is the sole marketer and has provided Special Contract Prices to customers. Such adjustments shall be made in accordance with SB contract Policy and Procedure document SB's Contract Policies and Procedures attached to this Agreement as Addendum I and incorporated by reference.

C. Terms*Payment by Check*

SB shall provide a cash discount of 2% off SB's invoices ~~(after deduction of all SB authorized credit memos excluding tax and chargeback credit memos)~~ for cash payments postmarked and mailed to SB no later than thirty (30) days from date of invoice. In the case of automatic shipments, SB shall provide a 2% cash discount when payment is postmarked and mailed within the time period specified on the invoice.

Payments by EFT (Electronic Funds Transfer)

SB shall provide a discount of 2% off SB's invoices ~~(after deduction of all SB authorized credit memos excluding tax and chargeback credit memos)~~ for electronic funds transfer value received no later than thirty-four (34) days (invoice terms, plus 4 days) from the date of invoice. In the case of automatic shipments, SB shall provide a 2% cash discount when payment is received within the time period specified on the invoice, plus 4 days.

D. Transportation Charge Prepayment

SB shall prepay all transportation charges on orders when routing is done at SB's discretion. If WHOLESALER requests special routing and SB approves of the routing which results in higher transportation cost than would be incurred as a result of the routing of SB's choice, then the difference in the transportation cost shall be borne by WHOLESALER.

E. Returns

SB shall accept for credit any SB products returned from WHOLESALER'S inventory. Returns of WHOLESALER'S stock will be credited at the price when purchased. In accordance with SB's existing practices, authorized credits for returns are subject to a 2% reduction for discounts taken from the original invoice price. (See Sections I(C) and II(A) for application of credits.) Except for returns resulting from shipping and/or ordering errors, SB will not accept any opened or unopened package returns taken back by the WHOLESALER from its customers. Freight charges that are a result of returns are the responsibility of the WHOLESALER. Furthermore, SB will not accept merchandise that has been altered by repackaging. All returns over \$10,000 require prior approval by the SB Trade Account Manager or the Customer Satisfaction Consultant at 1-800-877-1158.

F. Product Recalls

SB shall compensate WHOLESALER for the expense incurred in performing all requested recall services. Such compensation shall be limited to expenses incurred for recall services directly related to WHOLESALER'S inventory in WHOLE-

SALERS possession unless SB requests additional recall services in writing from WHOLESALER.

G. Product Liability Protection

SB shall guarantee that all SB products meet standards of identity, strength, quality and purity in their manufacture. If a claim is made against the WHOLESALER as a result of distributing an SB product, SB will, subject to the following conditions, provide legal defense—including the payment of all reasonable expenses and attorney fees—and assume any judgment liability. This guarantee is conditioned on SB being promptly notified of any claim, or the service of any complaint, and the full cooperation of the WHOLESALER, including complete access to all relevant records.

This protection does not apply if the claim results from any negligent, improper or illegal act, or failure to act on the part of the WHOLESALER, or if the Product had been repackaged or had not been properly stored, handled or distributed.

II. OBLIGATIONS OF WHOLESALER:

A. Payment for Products

WHOLESALER shall pay for all regular orders purchased by WHOLESALER, with payment to be received by SB no later than thirty (30) days for cash payments or thirty-four (34) days for EFT payments from the date of invoice, or in the case of automatic shipments or other extended billing purchases, within the terms specified on the invoice, plus four (4) days for EFT. As provided in I(C) above, SB will provide a 2% cash discount off SB's invoices (~~after deduction of selected credit memos described in the SB WHOLESALER Price List~~) for

cash payment received thirty (30) days and EFT payments received by thirty-four (34) days after date of invoice. In the case of automatic shipment purchased, SB will provide a 2% cash discount for payment received within the time period specified on the invoice statement, plus four (4) days for EFT. *All invoices must be paid in full under the terms specified above and no deductions, other than the cash discount, are permitted from SB invoices unless authorized by a prior credit memo.* Any late payments SB receives shall accrue interest at the maximum rate allowed by law.

B. Financial and Credit Position

WHOLESALE shall maintain an adequate financial condition satisfactory to SB and substantiate such a condition with audited financial statements or as otherwise requested by SB. If, in SB's judgment, at anytime before shipment, the financial condition of the WHOLESALE becomes impaired or unsatisfactory to SB, SB may require cash payment or appropriate security before shipment. If WHOLESALE experiences any event that adversely impacts its financial condition, including, for instance and without limitation, a loss of a significant contract, a write-off of a significant receivable or any event impacting 3% or more of WHOLESALE's revenues, net profits or working capital, WHOLESALE shall provide SB with written notice of such change in financial condition within 24 hours of its occurrence.

C. Payment of Unearned Cash Discounts

WHOLESALE shall reimburse SB for any cash discounts taken but not earned. SB will issue a second invoice for the Unearned Cash Discount for

which WHOLESALER shall make payment upon receipt of invoice.

D. Ordering

1. WHOLESALER shall transmit SB orders either direct or, if indirect, via Informatics Ordernet Clearinghouse, using the SB automated order entry system.
2. WHOLESALER shall place orders as follows:
 - a. Not more than ~~four~~(4) one stock orders transmitted within each ~~month~~ week, unless otherwise approved by SB in Philadelphia. Drop-shipments will be handled on an individual basis and must be approved by SB;
 - b. Unlimited orders for new selected products, strengths or sizes (referred to below as new SB items) which WHOLESALER places during the first sixty (60) days after their introduction:
 - c. Telephone orders only in emergencies, and limited to ten (10) line items with a limit of one case per line item. WHOLESALER will pay a charge of \$35.00 for emergency orders; this charge will not apply to orders due to SB out-of-stock situation.

E. Inventory

1. WHOLESALER shall purchase exclusively from SB or an authorized distribution of SB or an authorized distributor of SB all requirements of SB products and maintain at all times an inventory of those SB MUST STOCK items designated in SB's then current Wholesale Price List, at such a level that WHOLE-SALER'S

total out-of-stocks for such line items will not exceed six (6) in any month. Intra-company transfers between distribution centers are allowable.

2. SB can request, at any time, information regarding inventory levels of any SB product. This information can be compiled from either computer records or actual physical inventory count by an authorized SB representative.
3. SB requires that WHOLESALER shall report as soon as reasonably possible their sales of SB products to IMS Health (DDD).

F. Services

1. WHOLESALER shall provide aggressive sales support for SB Products as well as the order-taking, question-answering and delivery services necessary to meet reasonable needs of customers for these products.
2. WHOLESALER shall credit applicable WHOLESALER Customers for products returned directly to SB by WHOLESALER'S customers for which SB has issued a return goods credit memo to WHOLESALER.
3. WHOLESALER shall provide prompt marketing and stocking of new SB items for customers.

G. Special Contract Pricing

1. WHOLESALER shall hold in confidence and not disclose, directly or indirectly, to any third party (other than the entity soliciting such quotations), any information concerning any Special Contract Prices quoted by either WHOLESALER or SB in bidding for a contract

sale, so long as a product award has not been issued by the party soliciting such quotations. (As in the case of any material breach, a violation of this provision shall constitute grounds for immediate termination as an SB distributor.)

2. WHOLESALER shall comply with the SB contracts SB's Contracts Policies and Procedures attached to this Agreement as Addendum I.
3. WHOLESALER shall provide SB with electronic chargeback owed to the WHOLESALER at the end of each week, month or quarter. SB will credit the WHOLESALER for such chargeback.
4. See attached insert.

H. Lawful Handling

1. With respect to SB products, WHOLESALER shall take such precautions as are necessary to prevent them from falling into the hands of those who may not lawfully possess or handle them, and fully comply with local, state and federal laws.
2. WHOLESALER shall maintain all federal, state and local registrations necessary for the lawful handling of all SB products and immediately notify SB of any denial, revocation or suspension of any such registration or any changes in the SB products which WHOLESALER is authorized to distribute.
3. WHOLESALER shall immediately report to SB any in-transit loss or shortage of SB products including controlled substances.

4. WHOLESALER shall report any administrative, civil or criminal action by local, state or federal authorities against WHOLESALER, its officers or employees, regarding alleged violations of the Controlled Substance Act of 1970, as amended or other comparable legislation, and shall provide SB with complete information concerning the disposition of such action.

I. Proper Handling and Storage

WHOLESALER shall handle and store SB products in a clean and orderly location and in a manner that will assure that the proper rotation and quality of such products are maintained. WHOLESALER shall comply with SB criteria on shipping products that require special handling. WHOLESALER shall allow SB to conduct a physical inspection of WHOLESALER's storage facilities at any time SB requests.

J. Substitution

WHOLESALER shall fill orders for SB products, only with SB products. WHOLESALER shall not substitute any orders for SB Products with product not manufactured by SB.

K. Transfer of Ownership—Change in Address

WHOLESALER shall notify SB of the terms and conditions of any transfer in majority ownership or control, or any change in address, at least thirty (30) days prior to such action.

L. Automatic Shipments

WHOLESALER shall accept automatic shipments of reasonable quantities of new SB items including those distributed on an extended billing basis. SB

reserves the right to determine the size of such shipments.

M. Claims

WHOLESALE shall report all claims within fourteen (14) days of the receiving date. Proper documentation must accompany the claim. Deductions on damaged goods, shortages or shipping errors will not be allowed. SB will issue credit to the WHOLESALE. Unless SB fails to provide credit within 30 days of notification by WHOLESALE.

N. Audit or Review and Payment of Prior Transactions

WHOLESALE must submit all requests for review or payment of prior transactions within twelve (12) months of the transaction date.

III. GENERAL PROVISIONS

- A.** All orders are subject to acceptance and approval by SB at its central Distribution Office in Philadelphia, Pennsylvania.
- B.** This Agreement may be terminated by either party immediately upon any material breach of the terms of this Agreement by the other.
- C.** Neither SB nor WHOLESALE shall be liable to the other for failing to do as agreed where such failure is the result of a strike or other labor disturbance, fire, flood, earthquake, storm, governmental action, or other reason beyond its control.
- D.** The relationship created by this Agreement is a buyer-seller relationship and not an agency relationship.

- E. Title to products shipped to WHOLESALER will pass when delivered by SB to carrier.
- F. In the event there is a shortage of any SB product, SB shall have the right to prorate such product among its WHOLESALERS in such a manner as it, in its sole discretion, deems to be in the public interest.
- G. SB reserves the right to fill only as much of a WHOLESALER'S product order as SB, in its sole discretion (after conferring in, good faith with WHOLESALER), determines represents WHOLESALERS bona fide current requirements for such product, and SB may exercise such right whether or not it has announced a forthcoming price increase for such product.
- H. This Agreement shall not be construed as limiting WHOLESALERS lawful right to choose such customers and charge such prices as WHOLESALER freely determines or as granting to WHOLESALER exclusive rights in any territory.
- I. This Agreement may be changed or amended only in writing signed by duly authorized representatives of SB and WHOLESALER, and in the case of SB, only by a representative from its office in Philadelphia. All attachments and addenda to this Agreement are hereby incorporated by reference.
- J. This Agreement shall not be assigned or otherwise transferred without SB's prior written consent.
- K. This Agreement shall terminate automatically on December 31, 2000, or at any subsequent date specified in writing by SB. During its term, the Agreement may be terminated by either party on thirty days' written notice mailed to the other at the address set forth above.

- L.** Payment for SB products shipped but not invoiced at the time termination of this Agreement becomes effective and any outstanding invoices or advance chargeback credits shall become due immediately upon termination.
- M.** This Agreement supersedes all prior contracts, agreements and understandings between SB and WHOLESALER.
- N.** This Agreement shall be construed in accordance with, and governed by, the laws of the Commonwealth of Pennsylvania.
- O.** Terms of this Agreement apply to those distribution centers located in the Continental United States, Alaska and Hawaii.
- P.** Unauthorized deductions are in violation of this Agreement and will result in delayed shipments.
- Q.** During the term of this Agreement and for a period of one year thereafter, WHOLESALER shall maintain documentation of all sales of SB products, including documentation of the purchaser of such products and WHOLESALER's payment to SB for such products (together, the "Documentation"). SB shall have the right, upon reasonable prior written notice to WHOLESALER, to audit all Documentation at WHOLESALER's primary place of business during normal working hours for purposes of assuring the appropriateness of any and all payments made or reimbursement claimed and/or paid under this Agreement and to assess WHOLESALER's performance under this Agreement, and shall have the right to audit the systems and processes used by WHOLESALER to assure that sales and calculations are performed accurately in accordance with the terms of this Agreement. SB

agrees that such audits will only be conducted by SB employees or an authorized representative.

- R. WHOLESALER represents and warrants that, to the best of its information and belief that the computer hardware and software systems used by WHOLESALER in supplying orders or other information to SB pursuant to this Agreement are, or shall be by ~~May~~ June 1, 1999, Year 2000 compliant, and that the continuity and quality of supply of orders or other information to SB will not be affected by the failure of WHOLESALER's systems due to any Year 2000 non-compliance. WHOLESALER shall provide any required additions or modifications to the design and performance specifications of WHOLESALER to ensure compliance with this warranty at no cost to SB. In addition to any other rights or remedies available to SB under this Agreement, WHOLESALER's obligation and SB's remedy for any breach of this warranty, or upon notification by WHOLESALER that the WHOLESALER's internal systems shall not be Year 2000 compliant by the date specified in this warranty, shall be, at SB's discretion, one or more of the following: 1) WHOLESALER shall take all reasonable steps to minimize the impact of any Year 2000 non-compliance by the WHOLESALER's internal systems on the continuity and quality of supply of orders or other information to SB, and shall afford SB at least equal priority with WHOLESALER's other preferred customers in maintaining the continuity and quality of supply of orders or other information to SB; 2) WHOLESALER shall make any necessary repairs or replacements to WHOLESALER's internal systems in order to correct the breach within 30 days of receiving written notice from SB to do the same; 3)

SB may revise or restrict WHOLESALER's credit line or require cash payment or appropriate security before shipment; and/or 4) SB may terminate this Agreement.

- S. Nothing in this Agreement or the conditions of sale of product to WHOLESALER shall be construed as granting or implying the grant of any license under any patent or trademark rights or any other industrial property rights held by SB or any of its affiliates anywhere in the world outside of the U.S., and SB shall be entitled to exercise such patent or trademark rights and/or other industrial property rights to the fullest extent legally permissible at the time of such exercise. Unless authorized, no trademarks of which SB or any of its affiliates are proprietors or authorized users shall be applied to any goods originally supplied by them on removal from their original container except by a Pharmacist in the course of dispensing a prescription endorsed by a qualified medical practitioner to indicate the name of the product on the container, or by a medical practitioner dispensing their own prescriptions. In the case where a trademark was on the goods when originally supplied by them, this trademark shall not be altered, partly removed or partly obliterated. All subsequent purchasers shall be put on notice of these reservations and shall be required to put any further subsequent purchasers on like notice. In the case where trademark was [illegible] the goods when originally supplied by the WHOLESALER SB agrees to provide legal defense—including the payment of all expenses and attorney fees—and assume any liability for judgement based on any alleged breach of any such patent or trademark rights by WHOLESALER.

IN WITNESS WHEREOF, the parties hereto have executed this WHOLESALER DISTRIBUTION AGREEMENT as of the date set forth above.

WHOLESALER

SMITHKLINE BEECHAM
PHARMACEUTICALS
Division of SmithKline
Beecham Corporation
Philadelphia, Pennsylvania

/s/

/s/

By _____
Authorized Representative

By _____
Vice President and Director
Trade & Pharmacy Affairs -
U.S.

Title: President

Date: July 19, 1999

Date: _____

ATTACHMENTS

Addendum I: Contract Policies and Procedures

EXHIBIT C Impact of Prior Authorization Augmentin Analysis						
Historical Share and Dollar Impact Analysis of a PA Placed on Augmentin at Regional MCO in Nevada						
Unit and DACON WeightedRx Average WAC	\$ 80.00	Augmentin TRx's	Augmentin Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
3Q98		3900	46%		\$ 312,00	
4Q98		4053	49%	6.5%	\$ 324,240	
1Q99		3599	23%	-50.0%	\$ 287,920	\$ 36,320
2Q99		645	18%	-60.9%	\$ 51,600	\$ 272,640
Total Loss in Gross Revenue to Plan					\$	\$ 308,960
Percent Loss in Plan Market Share						-60.9%

Assumptions

TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.
Percent Loss in Plan Market Share = variance between 3Q98 and 2Q99 plan market shares
Gross Revenue calculated by multiplying TRx's by average price per indication treated.

EXHIBIT D Impact of Prior Authorization Paxil Analysis						
Historical Share and Dollar Impact Analysis of a PA Placed on Paxil at National MCO						
Unit and DACON WeightedRx Average WAC	\$ 66.89	PAXIL TRx's	Paxil Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
1Q97		40452	21%		2,705,834	
2Q97		32883	17%	-20.7%	2,199,544	\$ 506,290
3Q97		24354	15%	-29.9%	1,629,039	\$ 1,076,795
4Q97		20805	14%	-32.3%	1,391,646	\$ 1,314,188
1Q98		23811	14%	-35.4%	1,592,718	\$ 1,113,116
2Q98		23979	14%	-35.2%	1,603,955	\$ 1,101,879
3Q98		25668	13%	-36.8%	1,716,933	\$ 988,902
4Q98		26070	12%	-41.8%	1,743,822	\$ 962,012
Total Loss in Gross Revenue to Plan						\$ 7,063,183
Percent Loss in Plan Market Share						-41.8%

Assumptions

TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.

Gross Revenue calculated by multiplying TRx's by Unit and DACON weighted price per month

EXHIBIT E Impact of Prior Authorization Ralafen Analysis						
Historical Share and Dollar Impact Analysis of a PA Placed on Ralafen at Large West Coast based MCO						
Unit and DACON WeightedRx Average WAC	\$ 63.36	Ralafen TRx's	Ralafen Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
4Q97		12993	12.8%		\$ 823,236	
1Q98		12361	9.4%	-26.6%	\$ 783,193	\$ 40,044
2Q98		7856	6.6%	-48.9%	\$ 497,756	\$ 325,480
3Q98		6612	6.5%	-49.2%	\$ 418,936	\$ 404,300
4Q98		6372	6.3%	-50.8%	\$ 403,730	\$ 419,507
1Q99		6036	5.2%	-59.4%	\$ 382,441	\$ 440,796
2Q99		6036	4.9%	-61.7%	\$ 382,441	\$ 440,796
3Q99		6189	4.6%	-64.1%	\$ 392,135	\$ 431,101
4Q99		5664	4.2%	-67.2%	\$ 358,871	\$ 464,365
Total Loss in Gross Revenue to Plan						\$ 2,966,388
Percent Loss in Plan Market Share						-67.2%

Assumptions

TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.

Gross Revenue calculated by multiplying TRx's by Unit and DACON weighted price per month

EXHIBIT F Impact of Prior Authorization Avandia Analysis						
Historical Share and Dollar Impact Analysis of a PA Placed on Avandia at MCO Plan						
Unit and DACON WeightedRx Average WAC	\$ 87.49	Avandia Plan Market Share	Percent Change in Market Share	Gross Revenue	Estimated Gross Sales without PA	Total Loss in Revenue with PA Disadvantage Avandia
Jan-00		61%		\$ 28,434		
Feb-00		55%		\$ 31,234		
Mar-00		36%	-34.5%	\$ 39,545	\$ 60,417	\$ (20,871)
Apr-00		30%	-46.0%	\$ 40,858	\$ 75,663	\$ (34,805)
Total Loss in Gross Revenue to Plan						\$ (55,676)
Percent Loss in Plan Market Share						46.0%

Assumptions
Customer has a 70/30 Actos vs Avandia market share split with the PA disadvantaging Avandia
Avandia market share is restated to reflect a 2 product market.
Gross Revenue with PA calculated by multiplying TRx's by Unit and DAICON weighted price per month.
Estimated Gross Sales without a PA is calculated by dividing TRx's by Avandia Market Share and multiplying that sum by a 55% market share and DAICON weighted price per month.
Percent Loss in Plan market share calculated as a variance between Feb 2000 market share of 55% and April 2000 market share of 30%.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH)	
AND MANUFACTURERS OF)	
AMERICA,)	Civil Action No.
)	<u>00-157-B</u>
Plaintiff,)	
)	
v.)	
KEVIN CONCANNON, in his official)	
Capacity as Commissioner of the)	
Department of Human Services)	
For the State of Maine)	
ANDREW KETTERER, in his official)	
capacity as Attorney General)	
for the State of Maine)	
Defendants.)	

DEFENDANTS' ANSWER

The defendants, Kevin Concannon, Commissioner of the Department of Human Services for the State of Maine, and Andrew Ketterer, the Attorney General for the State of Maine, each named in their official capacities, by and through their counsel, the Attorney General for the State of Maine, answer Plaintiff's complaint as follows:

1. The allegations set forth in paragraph 1 of the complaint are legal in nature and do not require a response.
2. The Act speaks for itself. The allegations set forth in paragraph 2 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

3. The Act speaks for itself. The allegations set forth in paragraph 3 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

4. Defendants deny the allegations set forth in paragraph 4 of the complaint.

5. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 5 of the complaint.

6. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 6 of the complaint.

7. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 7 of the complaint.

8. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 8 of the complaint.

9. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 9 of the complaint.

10. Defendants admit the allegations set forth in paragraph 10 of the complaint.

11. Defendants admit the allegations set forth in paragraph 11 of the complaint.

12. Defendants admit the allegations set forth in paragraph 12 of the complaint.

13. Defendants admit the allegations set forth in paragraph 13 of the complaint.

14. The allegations set forth in paragraph 14 of the complaint are legal in nature and do not require a response.

15. The allegations set forth in paragraph 15 of the complaint are legal in nature and do not require a response.

16. The allegations set forth in paragraph 16 of the complaint are legal in nature and do not require a response.

17. Defendants deny the allegations set forth in paragraph 17 of the complaint, except defendants admit that the Act enacts a new Chapter 603, entitled “Prescription Drug Access,” in Maine Rev. Stat. Ann. Title 22.

18. The Act speaks for itself. The allegations set forth in paragraph 18 of the complaint are legal in nature and do not require a response.

19. The Act speaks for itself. The allegations set forth in paragraph 19 of the complaint are legal in nature and do not require a response.

20. Defendants admit that Maine residents who do not have prescription drug coverage under other public or private program will qualify for the Maine Rx Program to be administered by the Department, and that the number of such residents is presently estimated at 325,000. Otherwise, the allegations set forth in paragraph 20 of the complaint are denied.

21. The Act speaks for itself. The allegations set forth in paragraph 21 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

22. The Act speaks for itself. The allegations set forth in paragraph 22 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

23. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 23 of the complaint.

24. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 24 of the complaint.

25. The Act speaks for itself. The allegations set forth in paragraph 25 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

26. The Act speaks for itself. The allegations set forth in paragraph 26 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

27. The Act speaks for itself. The allegations set forth in paragraph 27 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

28. Defendants deny the allegations set forth in paragraph 28 of the complaint, except Defendants admit that on August 2, 2000 the Commissioner sent to pharmaceutical manufacturers a "Rebate Agreement" which defines the rebate amount being sought as equal to the Medicaid rebate, and that the Commissioner requested that executed Rebate Agreements be returned to the Department by November 1, 2000.

29. The Act speaks for itself. The allegations set forth in paragraph 29 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

30. The Act speaks for itself. The allegations set forth in paragraph 30 of the complaint are legal in nature and do not require a response, but to the extent they do require a response they are denied.

31. Defendants deny the allegations set forth in paragraph 31 of the complaint.

32. The Act speaks for itself. The allegations set forth in paragraph 32 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

33. The Act speaks for itself. The allegations set forth in paragraph 33 of the complaint are legal in nature and do not require a response.

34. The Act speaks for itself. The allegations set forth in paragraph 34 of the complaint are legal in nature and do not require a response, but to the extent they require a response, they are denied.

35. The Act speaks for itself. The allegations set forth in paragraph 35 of the complaint are legal in nature and do not require a response.

36. Defendants admit the allegations set forth in paragraph 36 of the complaint.

37. The relevant Acts speak for themselves. The allegations set forth in paragraph 37 of the complaint are legal in nature and do not require a response.

38. The Act speaks for itself. The allegations set forth in paragraph 38 of the complaint are legal in nature and do not require a response.

39. The Act speaks for itself. The allegations set forth in paragraph 39 of the complaint are legal in nature and do not require a response.

40. The Act speaks for itself. The allegations set forth in paragraph 40 of the complaint are legal in nature and do not require a response, but to the extent they require a response, they are denied.

41. The Act speaks for itself. The allegations set forth in paragraph 41 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

42. The Act speaks for itself. The allegations set forth in paragraph 42 of the complaint are legal in nature and do not require a response.

43. The Act speaks for itself. The allegations set forth in paragraph 43 of the complaint are legal in nature and do not require a response.

44. The Act speaks for itself. The allegations set forth in paragraph 44 of the complaint are legal in nature and do not require a response.

45. The Acts speak for themselves. The allegations set forth in paragraph 45 of the complaint are legal in nature and do not require a response.

46. The Act speaks for itself. The allegations set forth in paragraph 46 of the complaint are legal in nature and do not require a response.

47. The “Medicaid” Act speaks for itself. The allegations set forth in paragraph 47 of the complaint are legal in nature and do not require a response.

48. The Omnibus Budget Reconciliation Act of 1990 speaks for itself. The allegations set forth in paragraph 48 of the complaint are legal in nature and do not require a response.

49. The “Medicaid” Act speaks for itself. The allegations set forth in paragraph 49 of the complaint are legal in nature and do not require a response.

50. The “Medicaid” Act speaks for itself. The allegations set forth in paragraph 50 of the complaint are legal in nature and do not require a response.

51. The “Medicaid” Act speaks for itself. The allegations set forth in paragraph 51 of the complaint are legal in nature and do not require a response.

52. The “Medicaid” Act speaks for itself. The allegations set forth in paragraph 52 of the complaint are legal in nature and do not require a response.

53. The “Medicaid” Act speaks for itself. The allegations set forth in paragraph 53 of the complaint are legal in nature and do not require a response.

54. Paragraph 54 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

55. The allegations set forth in paragraph 55 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

56. The allegations set forth in paragraph 56 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

57. Defendants deny the allegations set forth in paragraph 57 of the complaint.

58. Defendants deny the allegations set forth in paragraph 58 of the complaint.

59. Paragraph 59 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

60. The allegations set forth in paragraph 60 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

61. Defendants deny the allegations set forth in paragraph 61 of the complaint.

62. Defendants deny the allegations set forth in paragraph 62 of the complaint.

63. Defendants deny the allegations set forth in paragraph 63 of the complaint.

64. Paragraph 64 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

65. The allegations set forth in paragraph 65 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

66. Defendants deny the allegations set forth in paragraph 66 of the complaint.

67. Defendants deny the allegations set forth in paragraph 67 of the complaint.

68. Defendants deny the allegations set forth in paragraph 68 of the complaint.

69. Paragraph 69 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

70. The allegations set forth in paragraph 70 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

71. Defendants deny the allegations set forth in paragraph 71 of the complaint.

72. Defendants deny the allegations set forth in paragraph 72 of the complaint.

73. Defendants deny the allegations set forth in paragraph 73 of the complaint.

74. Paragraph 74 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

75. The allegations set forth in paragraph 75 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

76. Defendants deny the allegations set forth in paragraph 76 of the complaint.

77. Defendants deny the allegations set forth in paragraph 77 of the complaint.

78. Defendants deny the allegations set forth in paragraph 78 of the complaint.

79. Paragraph 79 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

80. Defendants admit the allegations set forth in paragraph 80 of the complaint.

81. Defendants deny the allegations set forth in paragraph 81 of the complaint.

82. Defendants deny the allegations set forth in paragraph 82 of the complaint.

DEFENSES

1. Plaintiff's claims are barred by the Market Participation exception to the Commerce Clause.

2. Plaintiff's claims are not ripe.

3. Plaintiff's claims are not justiciable under Article III of the United States Constitution.

4. Plaintiff's complaint fails to state a claim or claims upon which relief may be granted.

5. Plaintiff lacks standing to bring the claims alleged in the complaint.

6. The defendants are sued in their official capacities. To the extent Plaintiff seeks damages, such an action is barred by the Eleventh Amendment and the doctrine of sovereign immunity.

Dated: September 11, 2000 ANDREW KETTERER
Augusta, Maine Attorney General

by: /s/
 Andrew S. Hagler
 Assistant Attorney
 General
 6 State House Station
 Augusta, Maine 04333
 (207) 626-3800
 Attorney for the
 Defendants

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA

Plaintiff

v.

Civil Action No.
00-157-B

KEVIN CONCANNON, in his official
capacity as Commissioner of the
Department of Human Services
For the State of Maine
and

ANDREW KETTERER, in his official
capacity as Attorney General
For the State of Maine

Defendants.

AFFIDAVIT OF TIMOTHY S. CLIFFORD, M.D.

TIMOTHY S. CLIFFORD, M.D., being duly sworn,
deposes and says that the following is true and correct and
based upon personal knowledge:

1. My name is Dr. Timothy S. Clifford. Since April, 1996,
I have been the Medical Director for the Maine Bureau of
Medical Services, which administers the state's Medicaid
Program. I am also a practicing Family Physician in
Bucksport, Maine with 15 years experience.

2. In my role as Medicaid Medical Director I decide, in
conjunction with the Maine Medicaid Drug Utilization
Review ("DUR") Committee, which drugs are to be prior
authorized and under which conditions particular requests for
prior authorization will be granted. I personally review all

drug prior authorization requests which require the clinical determination of a physician.

3. I have read the declaration submitted by Dr. Scott Howell on behalf of the plaintiff in this action.

4. I disagree with Dr. Howell's suggestion that, when a particular drug is subject to a prior authorization requirement, physicians and pharmacists must obtain permission each time that drug is prescribed or dispensed to a particular patient.

5. The Maine Medicaid program does not require a physician to seek permission each time they wish to prescribe a drug subject to a prior authorized requirement. For the vast majority of drugs with prior authorization requirements, an authorization obtained from my office will permit a pharmacy to dispense that drug to that patient for as many times as the physician finds medically necessary, within a 6-12 month period. A smaller percentage of other drugs with prior authorization requirements may be prescribed, as deemed necessary by the physician, within a 3 month period. Only if specifically requested by the physician will the authorization obtained from my office be limited to less than 3 months.

6. I also disagree with Dr. Howell's suggestion that the purpose of imposing a prior authorization requirement on the use of a particular drug is to limit the use of that drug.

7. The primary purpose of a prior authorization requirement is to ensure that a drug is not being used inappropriately.

8. I also disagree with Dr. Howell's suggestion that the Department will not address safety and efficacy concerns in administering the prior authorization mechanism of the Maine Rx Program. I further disagree with the suggestion that the Department will not consider the availability of alternative drugs in making the decision of whether to subject a particular drug to a prior authorization requirement. Finally, I disagree with Dr. Howell's conclusion that the Department's

implementation of the prior authorization mechanism of the Maine Rx Program will limit the access of Medicaid recipients to medically necessary drugs.

[9]. The Maine Medicaid Program always has considered, and the Maine Rx Program always will consider, the safety, efficacy and availability of other drugs in its implementation of the prior authorization process. The Department certainly will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturers participates in Maine Rx Program by entering into rebate agreements. The Department has drafted proposed administrative rules governing the use of the prior authorization provision of the Maine Rx Program. These rules require that the determination of whether a particular drug should be subjected to a prior authorization requirement be made by physicians and pharmacists sitting on the Maine Medicaid Drug Utilization Review Committee. These rules also require that the determination of whether a particular drug should be subjected to a prior authorization requirement will be based firmly upon considerations of medical necessity, and in compliance with the State's responsibilities as the administrator of the Maine Medicaid Program.

[10]. I also disagree with Dr. Howell's statement that the Maine Rx Program prior authorization provision will be implemented so as to impose significant and gratuitous burdens on Medicaid healthcare providers and patients, and that patients will, as a result, be denied access to the safest and most efficacious drugs.

[11]. Physicians in Maine are already well acquainted with the extensive prior authorization programs of the four HMO/Insurance programs which collectively cover nearly half the state's residents. As explained above, in implementing the prior authorization provision of the Maine Rx Program, the Department will ensure that physicians will

always be able to prescribe the safest and most efficacious drugs for their Medicaid patients.

[12]. I also disagree with Dr. Howell's statement that prior authorization requirements cause doctors to switch from first-choice drugs to potentially less safe and effective second-choice drugs. The fundamental fallacy of this statement is the notion that the so-called "first choice" drug is always the safest and the most effective drug in all situations. A number of studies and Drug Utilization Review Programs have disproved this wildly inaccurate claim. For example, our Maine's Drug Utilization Review Program sends out nearly 1,000 letters a month to physicians warning them of potentially dangerous drug/drug and drug/disease interactions on recent prescriptions they have written and of which they are often unaware. Furthermore, our pharmacy point of purchase claims processing system alerts pharmacists to thousands of other dangerous drug/drug interactions, thereby preventing the filling of dangerous prescriptions. Thus, whether or not a prior authorization requirement applies to a specific drug, the "first choice" is often not the best choice. In fact, a well designed prior authorization program can improve safety and insure that the "first choice" drug is used appropriately.

[13.]. I also disagree with the claims Dr. Howell makes on behalf of his company's drug, *Augmentin*. Specifically, I disagree with Dr. Howell's attempt to suggest that the Centers for Disease Control unequivocally recommends *Augmentin*, for the treatment of *otitis media*, or ear infections.

[14]. In truth, the Centers for Disease Control recommended the broad spectrum antibiotic, *Augmentin*, as a second line medication in the treatment of ear infections only after an attempt to treat the condition with *Amoxicillin*, a far less expensive, and more "narrow band" antibiotic, have failed.

[15]. I also disagree with Dr. Howell's suggestion that implementation of the prior authorization provision of the Maine Rx Program will not involve a thoughtful process designed to achieve safety, efficacy, and cost-effectiveness in the dispensing of prescription drugs to Medicaid recipients.

[16]. The Department has in place adequate safeguards to ensure the best clinical treatment and safety of Medicaid patients. The Department currently employs two (2) full time pharmacists, two (2) part-time pharmacists and it contracts for the additional specialized services of four (4) other pharmacists. An active Drug Utilization Review Committee exists and that committee, and the Department, actively solicit and receive the advice from a variety of Health Maintenance Organizations, state and federal government agencies and health care professionals. In contrast to prior authorization programs established by private insurers, our program must comply with a variety of State and Federal laws and regulations which are in place to ensure that Medicaid recipients receive the drugs which are for them medically necessary. Accordingly, implementation of the prior authorization provision of the Maine Rx Program will involve the same thoughtful process we have always employed to ensure safety, efficacy, cost-effectiveness, so as to benefit all Medicaid recipients.

Dated: 9/7/00

/s/

TIMOTHY S. CLIFFORD, M.D.

STATE OF MAINE
KENNEBEC, ss

Before me this day personally appeared Timothy S. Clifford, M.D., who being duly sworn, deposes and says that the statements in the above affidavit of same, are true.

/s/

Name of Notary Public:

Notary Public, State of Maine

My Commission Expires:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH	*
AND MANUFACTURERS OF AMERICA	*
	*
Plaintiff,	*
v.	* Civil Action
	* No. 00-157-B
	*
KEVIN CONCANNON, Commissioner	*
Of Maine Department of Human	*
Services	*
	*
ANDREW KETTERER, Attorney General	*
State of Maine	*
	*
Defendants.	*
	*
* * * * *	*

AFFIDAVIT OF H. BURTT RICHARDSON, JR, M.D.

I, Burtt Richardson, being duly sworn, state as follows:

1. This affidavit is based upon my personal knowledge, information and belief.
2. My name is H. Burtt Richardson, Jr. I am a pediatrician and a Maine Medicaid provider. A current and accurate copy of my resume is attached as Exhibit A to this Affidavit.
3. I have been a Maine Medicaid provider for 22 years.
4. My practice can be broken down into the following categories: approximately 18% is Medicaid (including the Cub Care program); 30% is HMO (HealthSource, Blue Cross Blue Shield, etc.); 30% is insured with non-HMO's; 12% insured with high deductible (uninsured for primary care); and 10% are uninsured.

5. My practice ranks in the 72nd percentile of Maine pediatricians who treat Maine Medicaid children, in terms of the number of Medicaid-insured children seen per year.

6. I believe that most HMO's punish particular drug manufacturers who fail to negotiate competitive practices by disapproving certain drugs in their formularies.

7. The Maine Medicaid Program does not currently use the prior authorization of drugs to punish particular drug manufacturers for any reason.

8. I prescribe Augmentin as a second line drug after another drug, usually high dose amoxicillin, has failed to adequately treat an ear infection. Augmentin is 3 to 6 times as expensive as amoxicillin, and amoxicillin is effective in treating ear infections 80-85% of the time.

9. I know that some of my non-Medicaid patients cannot afford their medication. They have told me they were not able to purchase a prescription and they have asked for a less expensive alternative or a sample.

10. I have personally observed the parents of some of my non-Medicaid patients get my bill for service and show my bill to their children saying "see how much you cost us." I have observed that this scenario makes children feel guilty about being sick.

11. I welcome the Maine Rx Program law because it is attempting to reduce the price of drugs to some of my patients who do not have drug insurance benefits and who might otherwise not be able to afford medications.

12. I approve of the Maine Rx Program prior authorization procedure so long as the decision to put a prior authorization on particular drugs is clinically appropriate, feasible for a medical office, and accompanied by the assurance that all Maine Medicaid recipients have access to medically necessary drugs.

Dated: 9-7-00 /s/
H. Burt Richardson, Jr., M.D.

Personally appeared before me this 7th day of September, 2000, the above-named H. Burt Richardson, Jr., and made oath that the foregoing statements are true based upon his personal knowledge, information and belief.

Dated: 9/7/00 /s/
Notary Public/Attorney at Law
DONNA A. HEAVENER
Notary Public • State of Maine
My Commission Expires 2/13/07

[Exhibit A]

CURRICULUM VITAE

RICHARDSON, HENRY BURTT, JR., M.D., F.A.A.P.

Pediatrician
Winthrop Family Pediatrics Center
R.F.D. 3 Box 9
Winthrop, Maine 04364
Phone 207-377-2114

BORN: Passaic, New Jersey – November 20,
1934

CITIZENSHIP: U.S.A.

EDUCATION: Haverford College,
Haverford, Pennsylvania
Temple University School of
Medicine,
Philadelphia, Pennsylvania

DEGREES: A.B., Haverford College—June 1956
M.D., Temple University—June 1960

POST GRADUATE TRAINING:

July 1960—June 1961 Rotating Internship—State University
of New York,
Upstate Medical Center Hospitals,
Syracuse, New York

July 1961—June 1963 Residency in Pediatrics,
St. Christopher's Hospital for
Children,
Philadelphia, Pennsylvania